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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,448	10/24/2003	Robert C. Bohannon	018877-000122US	2899

20350 7590 05/04/2007

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
05/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,448	BOHANNON	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,4-6,9 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,4-6,9 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-6, 9, 12-15 are pending and under consideration.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/010,903, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. said application does not disclose the induction of endogenous antibodies as an antidote for anti-neoplastic agents, therefore the effective priority date f the instant application will be February 28, 1994.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1, 4-6, 9 and 12-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The instant claims are drawn to a method for suppressing or reducing the physiological effects caused by an anti-neoplastic drug, and a method for reducing the toxicity of an anti-neoplastic compound, both methods comprising administering prior to the administration of said drug, a drug-conjugate immunogen to elicit in the recipient, the production of anti-drug antibodies.

The instant claims require the administration if the drug conjugated immunogen prior to the administration of the anti-neoplastic drug. One of skill in the art would administer anti-neoplastic drugs to patients having cancer. thus, the instant claims require the development of humoral immunity against the anti-neoplastic compound. The art corroborates the fact that B cells recognize the hapten apart from the carrier, in the case the anti-neoplastic compound, rather than the hapten in the context of a protein carrier (Roitt et al, Immunology (text) 1998, page 142, second column, lines 11-12). It is reasonable to concluded that cancer patients subjected to the instant methods would have humoral immunity to the same anti-neoplastic compounds. The art teaches that it is routine and necessary to administer multiple rounds of cancer treatments in order to cause disease regression or stabilization. Schlom ('Monoclonal Antibodies: They're More and Less Than You Think', In: Molecular Foundations of Oncology, 1991, Broder, Ed., page 98, second column, second full paragraph) teaches that in the case of an administered murine antibody, the patient develops antibodies against the administered antibody and that by the third dose, the anti-HAMA antibodies of the patient prevented the administered antibody from reaching the targeted site. In the instant case, administration of the anti-neoplastic compound to the cancer patient previously immunized by the instant method claims, would result in a vastly decrease dose of anti-neoplastic compound that would persist for enough half life as a free anti-neoplastic compound to exert an efficacious effect against the cancer because the elicited antibodies would bind to the anti-neoplastic compound and it is well-known in the art

that antibody complexes are cleared from the blood stream. The specification does not address how to provide a pre-existing humoral immune response against the anti-neoplastic compound, wherein said humoral immune response would not interfere with the desired anti-neoplastic effect of said compound. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to use the claimed method with an efficacious result.

Applicant argues that antibodies have been used to reduce drug toxicity and cites two papers by Lobo et al in support for the enablement of the instant invention. this has been considered but not found persuasive. It is noted that the administration of Fab fragments to reduce peak plasma concentration of unbound drug were carried out solely for intraperitoneal chemotherapy, where the target lesions were in the peritoneum. The instant claims encompass any form of cancer, not just cancer within a body cavity. The specification does not describe the instant method as being applied to intracavity chemotherapy, such as intraperitoneal or intravesical chemotherapy. Further, the concept of using a neutralizing agent after intracavity chemotherapy has been attempted in the art. Markman et al (Western Journal of Medicine, 1985, Vol. 142, pp. 364-368), discusses the use of folinic acid in conjunction with intracavity administration of chemotherapeutic agents and states that the simultaneous administration of folinic acid and methotrexate runs the risk of neutralizing the methotrexate by diffusion of the folinic acid into the treated cavity, versus the administration of folinic acid after the treatment. In the instant case the humoral immune response could also neutralize the drug and decrease the available dose within the body cavity. It is noted that the administration of exogenous antibodies after the intracavity chemotherapy would have the advantage of not interfering with the availability of the chemotherapeutic agent in the body cavity. Because of the breathe of the claims which encompass cancers at all body locations, and the lack of teachings in the specification regarding the use of the instant method as an adjunct to intracavity chemotherapy, and the lack of teachings regarding the effect of a endogenous humoral immune response on the neutralization of a chemotherapeutic agent within a body cavity, one of skill in the art would be subject to undue experimentation without reasonable expectation of success to practice the broadly claimed method.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Balthasar and Fung, Journal of Pharmacology and Experimental Therapeutics, 1994, vol. 268, pp. 734-739.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
4/29/2007

KAREN A. CANELLA PH.D
PRIMARY EXAMINER